AUG 0 3 2004 W

PTO/SB/08a

Approved for use through 07/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| Complete if Known | | | | |
|------------------------|--------------------|--|--|--|
| Application Number | 10/717,925 | | | |
| Filing Date | November 21, 2003 | | | |
| First Named Inventor | William J. Carroll | | | |
| Art Unit | 3762 | | | |
| Examiner Name | Unknown | | | |
| Attorney Docket Number | 000309.00051 | | | |

| | U. S. PATENT DOCUMENTS | | | | | | |
|-----------|------------------------|---|------------------|-----------------------------|---|--|--|
| Examiner | Cite No.1 | Document Number | Publication Date | Name of Patentee or | Pages, Columns, Lines, Where | | |
| Initials* | | Number-Kind Code ^{2 (d known)} | MM-DD-YYYY | Applicant of Cited Document | Relevant Passages or Relevant Figures Appear | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | | • | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | | | | |
| | | US- | | 1 | | | |
| | | US- | | | | | |

2

| Examiner Initials* Cite Foreign Patent Document No.1 Country Code3- Number4 Kind Code5 (if known) Publication Date MM-DD-YYYY Applicant of Cited Document Where Relevant Passag Relevant Figures Applicant State of Cited Document Where Relevant Figures Applicant State of Cited Document Figures Applicant Figures Applicant Figures | | FOREIGN | PATENT DOCUMEN | ITS | | |
|--|------|---------|----------------|-----|---|---|
| | | | | | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | ぱ |
| | | | | | | |
| | | | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patient Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by symbols as indicated on the document wider WIPO Standard ST.18 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Acceptable, possessons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO Complete if Known Application Number 10/717,925 **INFORMATION DISCLOSURE** Filing Date November 21, 2003 STATEMENT BY APPLICANT First Named Inventor William J. Carroll (Use as many sheets as necessary) Art Unit 3762 Examiner Name Unknown Attorney Docket Number Sheet 000309.00051 2 of 2

| | | NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------|--------------|---|----|--|--|--|--|
| xaminer iitials* | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² | | | | |
| 56 | | MOHAMED A. HAMZA, M.D., et al., Effect of the Duration of Electrical Stimulation on the Analgesic Response in Patients with Low Back Pain, Anesthesiology, December 1999, pp. 1622-1627, Vol. 91, No. 6 | | | | | |
| | | EL-SAYED A. GHONAME, M.D., et al., The Effect of Stimulus Frequency on the Analgesic Response to Percutaneous Electrical Nerve Stimulation in Patients with Chronic Low Back Pain, Anesthesia & Analgesia, April 1999, pp. 841-846, Vol. 88, No. 4 | | | | | |
| | | RICHARD E. SEROUSSI, MD, et al., Effectiveness of Percutaneous Neuromodulation Therapy for Patients with Chronic and Severe Low Back Pain, 2003, pp. 22-30, Vol. 3, Issue 1, Pain Practice | | | | | |
| | | EL-SAYED A. CHONAME, MD, et al., Percutaneous Electrical Nerve Stimulation for Low Back Pain, JAMA, March 3, 1999, Vol. 281, No. 9 | | | | | |
| | | ANDREW J. ROBINSON, Clinical Electrophysiology, Electrotherapy and Electrophysiologic Testing, pp. cover, 285, 288-290, Second Edition, Williams & Wilkins | | | | | |
| | | M.I. JOHNSON, et al., An in-depth study of long-term users of transcutaneous electrical nerve stimulation (TENS). Implications for clinical use of TENS, Pain 41, 1991, pp. 221-229, Elsevier Science Publishers B.V. | | | | | |
| | | J.S. HAN, et al., Effect ov low- and high-frequency TENS on Met-enkephalin-Arg-Phe and dynorphin A immunoreactivity in human lumbar CSF, 1991, pp. 295-298, Elsevier Science Publishers B.V. | | | | | |
| | | ROGER M. NELSON, et al., Clinical Electrotherapy, third edition, Appleton & Lange, Stamford, Connecticut | | | | | |
| | | Vertis Percutaneous Neuromodulation Therapy (PNT), Peer Review Network, Inc., PRN Newsletter, November 2002, Vol. 9, No. 6., pp. 1-5 | | | | | |
| | | PRIYA GOPALKRISHNAN, MS, et al., Effect of Varying Frequency, Intensity, and Pulse Duration of Transcutaneous Electrical Nerve Stimulation on Primary Hyperalgesia in Inflamed Rats, Arch Phys Med Rehabil, Vol. 81, July 2000, pp. 984-990 | | | | | |
| | | M.I. JOHNSON, et al., Analgesic effects of different frequencies of transcutaneous electrical nerve stimulation on cold-induced pain in normal subjects, Pain 39 (1989), pp. 231-236, Elsevier Science Publishers B.V. | | | | | |
| V | | SERGE MARCHAND, M.Sc., et al., Modulation of Heat Pain Perception by High Frequency Transcutaneous Electrical Nerve Stimulation (TENS), The Clinical Journal of Pain, Vol. 7, No. 2, 1991, pp. 122-129 | | | | | |

| Examiner Signature | 5.6. | Date Considered | 1/30/06 |
|-----------------------|------|--------------------|---------|
| | | | |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language (ranslation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

JUN 2 2 2004 6.

PTO/SB/08a

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
no persons are required to respond to a collection of Information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of

| Complete if Ku | Complete if Known | | | | |
|------------------------|--------------------|--|--|--|--|
| Application Number | 10/717,925 | | | | |
| Filing Date | November 21, 2003 | | | | |
| First Named Inventor | William J. Carroll | | | | |
| Art Unit | 3762 | | | | |
| Examiner Name | Unknown | | | | |
| Attorney Docket Number | 000309.00051 | | | | |

| | | | U. S. PATENT D | OCUMENTS | |
|-----------|-----------|---|------------------|-----------------------------|---|
| Examiner | Cite No.1 | Document Number | Publication Date | Name of Patentee or | Pages, Columns, Lines, Where |
| Initials* | | Number-Kind Code ^{2 (d known)} | MM-DD-YYYY | Applicant of Cited Document | Relevant Passages or Relevant Figures Appear |
| 59 | | US-6,647,296 | 11/11/2003 | Fischell et al. | |
| | | US- | | | • |
| | | US- | | | |
| | | US- | | | . : |
| | | US- | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|--------------|--|--------------------------------|--|---|----------------|--|
| Examiner Initials* | Cite No.1 | Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ | |
| SE. | | PCT/US03/37372 International Search Report | 11/21/2003 | International Rehabilitative Sciences, Inc. | | | |
| | | | | | | | |
| | | | | | | _ | |

| Examiner | C 6. | Date Considered | 120 | 106 | |
|-----------|-------|--------------------|--------------|-----|---|
| Signature | J~ O+ | | <u> 1201</u> | 0.0 | _ |
| | | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

TO/SB/08b (08-03)
Approved for use through 08/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
ons are required to respond to a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction A
Substitute for form 1449A/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| Complete if Ki | | |
|------------------------|--------------------|--|
| Application Number | 10/717,925 | |
| Filing Date | November 21, 2003 | |
| First Named Inventor | William J. Carroll | |
| Art Unit | 3762 | |
| Examiner Name | Unknown | |
| Attorney Docket Number | 000309.00051 | |

| | | NON PATENT LITERATURE DOCUMENTS | |
|-----------------------|--------------|---|----|
| Examiner Initials* | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² |
| 56 | | KATAYAMA Y., Deep brain stimulation therapy for involuntary movements, Rinsho Shinkeigaku, 2001/12/01 00:00; 41(12):1079-80, 1 page | - |
| 1 | | BENABID AL, et al., Deep btrain stimulation of the corpus luysi (subthalamic nucleus) and other targets in Parkinson's disease. Extension to new indications such as dystonia and epilepsy, J. Neurol. 2001/09/01 00:00; 248 Suppl 3:III37-47, 2 pages | |
| | | ALLERT N., et al., Effects of bilateral pallidal or subthalamic stimulation on gait in advanced Parkinson's disease, Mov Disord. 2001/11/01 00:00; 16(6):1076-85, 2 pages | |
| | | UTTI RJ, et al., Extended Follow-up of Unilateral Deep Brain Stimulation for Tremor, Deep brain stimulation remains an effective treatment for tremor for at least 3 years, according to this article, P03.1123; A220-221 | |
| | | OBWEGESER AA, et al., Quantitative and qualitative outcome measures after thalamic deep brain stimulation to treat disabling tremors, Neurosurgery, 48(2): 274-81, discussion 281-4 2001, 2-page Article | |
| | | OBWEGESER AA, et al., Simultaneous thalamic deep brain stimulation and implanatable cardioverter-defibrillator, Mayo Clin Proc, 76(1): 87-9, 2001, 2-page Abstract | |
| | | OBWEGESER AA, et al., Thalamic stimulation for the treatment of midline tremors in essential tremor patients, Nekurology, 54(12): 2342-4 2000, 2-page Abstract | |
| | | OH MY, et al., Deep brain stimulator electrodes used for lesioning: proof of principle, Neurosurgery, 2001/08/01 00:00; 49(2): 363-7; discussion 367-9, 2-page Article | |
| , | | RACETTE BA, et al., Thalamic stimulation for primary writing tremor, J Neurol. 2001/05/01 00:00; 248(5): 380-2, 2-page Report | |
| V | | ROCCHI L, et al, Effects of deep brain stimulation and levodopa on postural sway in Parkinson's disease, J. Neuro Neurosurg Psychlatry, 2002 Sep; 73(3):267-74, 2-page Article | |

| Examiner Signature S - 6. Date Considered 1 30 06 | | | |
|---|------|----|-----|
| | | 30 | 106 |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw tine through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant Is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 06/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Applications are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| Complete if K | nown | | |
|------------------------|--------------------|--|--|
| Application Number | 10/717,925 | | |
| Filing Date | November 21, 2003 | | |
| First Named Inventor | William J. Carroll | | |
| Art Unit | 3762 | | |
| Examiner Name | Unknown | | |
| Attorney Docket Number | 000309.00051 | | |

| | | NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------|--------------------------|---|----|--|--|--|
| xaminer nitials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Τ² | | | |
| St | | NASSER JA, et al, Deep brain stimulation of VIM thalamic nucleus for tremor control, Arq Neuropsiquiatr. 2002 Jun; 60(2-8):429-34, 1-page Article | | | | |
| 1 | | RACETTE BA, et al., Ipsilateral thalamic stimulation after thalamotomy for essential tremor. A case report., Stereotact Funct Neurosurg. 2000/01/01 00:00; 75(4): 155-9, 2-page Article | | | | |
| | | RERZAI AR, et al., Neurostimulation systems for deep brain stimulation: in vitro evaluation of magnetic resonance imaging-related heating at 1.5 tesla, J Magn Reson Imaging, 2002/03/01 00:00; 15(3):241-50, 2-page Article | | | | |
| | | MAYA PINES, New Imaging Techniques That Show the Brain at Work: Brain Scans That Spy on the Senses, Seeing, Hearing, and Smelling the World, A Report from the Howard Hughes Medical Institute, 2-page Article | | | | |
| | | MAYA PINES, New Imaging Techniques That Show the Brain at Work: The Next Generation of Brain Scans, Seeing, Hearing, and Smelling the World, A Report from the Howard Hughes Medical Institute, 2-page Article | | | | |
| | | Oregon Imaging Article, P.E.T. Scan - Patient Information, 2 page Article | | | | |
| | <u> </u> | CIGNA CORPORATION, Positron Emission Tomography (PET) Scans - Medical Coverage, All States, 1999, 7-page Article | | | | |
| | | REZAI AR, et al., Neurostimulation systems for deep brain stimulation: in vitro evaluation of magnetic resonance imaging-related heating at 1.5 tesla, J magn Reson Imaging, 2002/03/01 00:00; 15(3):241-50, 2-page Article | | | | |
| | | MOBILE PET SYSTEMS, INC., Clinical Applications, 5-pages | | | | |
| V | | NEUROLOGICAL ASSOCIATES, INC., Deep Brain Stimulation, West Virginia, 6-page Article | | | | |

Examiner Signature Solution Signature Solution Signature Solution Signature Solution Solution

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.